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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,202	04/01/2002	Howard Tanner	23660-00623	2592

7590

12/04/2003

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Washington, DC 20007

EXAMINER
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ROBERTS, PAUL A

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 12/04/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Applicati n No.

09/936,202

Applicant(s)

TANNER ET AL.

Examiner

Paul A Roberts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 11-14 and 20-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 15-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 April 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's traversal of the group restriction is noted, but the traversal is not persuasive, because the arguments are not relevant to the requirements for restriction under rule 13.1 in appendix T. Since this application is a 371 of PCT/US00/03871, it is bound under the rules of unity of invention. Thus the classification arguments are irrelevant and so are the arguments about burden. However, the applicant argues that two technical features exist, the guideline component and at least one suture. The examiner contends these are not special features since a needle and a thread can be considered a guideline component and at least one suture. Thus the inventions lack unity and the restriction is proper is therefore made FINAL.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The material "Gore-Tex" is recited in claim 19. While the examiner is familiar with the material, the limitations of claim are unknown because no description or generic definition of the material was given. The use of the trademark "Gore-Tex" has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 8, 9, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Walker et al. (Walker) 5234445. Walker discloses a surgical guideline assembly comprising a guideline component 21 with a suture (27) secured to the distal end therein (shown in figure 5a). A control assembly (the trocar) is disclosed and permits manipulation of the guide assembly. The suture includes a needle. The guideline has central passage therein. The suture is secured within the guideline. Element 31 binds the suture to the guideline.
4. Claims 15 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Shave 5358498. Shave '498 discloses a guideline assembly comprising a guideline component 18, a suture (14) secured to the end of the guideline, a broadline (22) positioned around said distal end of said guideline component and a portion of the suture. A thin layer of material (that's the adhesive shown in figure 5) is positioned about said distal end of said guideline component and said at least one suture adjacent said broadline assembly.
5. Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Kammerer et al. (Kammerer) 5454820. Kammerer '820 discloses a guideline assembly comprising a guideline component 20, a suture (150) secured to the end of the guideline, a broadline (60) positioned around said distal end of said guideline component and a portion of the suture.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 4, 5, 6, 7, and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker '445 in view of Chan 5562687. Walker discloses a straight cannula having a suture therein. It is well known in the art to make cannulas curved because a curved cannula allows the surgeon reach certain areas inaccessible by straight catheters. Chan '687 discloses such a device. It is shown in figure 13. At the time of the invention it would have been obvious to one having ordinary skill in the art to use the Chan device to bend the Walker '445 cannula to allow the Walker device to be used in procedures inaccessible by straight-line cannulas. The bent or articulated section can be manipulated by the handle of the cannula (the trocar of figure 34).

7. Regarding claims 15-17, when the Walker '445 device is placed in the Chan '687 device, the limitations of claim 15 are met. As previously mentioned, Walker discloses the suture, needle, and guideline. The Chan device acts as the broadline assembly. The Chan device is positioned around the distal end of said guideline component and a portion of said suture. The broadline assembly produces a flexible curved end portion of said guideline assembly. Granted the broadline assembly of the applicant's device looks very different than that of the Chan '687 device, however those distinguishing features must be presented into the claim language for

those differences to be considered. As claimed, the Chan device meets the limitations of a broadline assembly.

8. Claims 4, 5, 6, 7, and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker '445, in view of Shroepel 6024764, in further view of Monter et al. 4290872.

Walker discloses a guideline assembly comprising a guideline and a suture secured therein.

Walker does not disclose a broadline assembly or the thin layer of material (sleeve). Schroeppel discloses one can add a shape-memory sleeve to a cannula to bend the cannula. There are many advantages to this practice. Schroeppel discloses his sleeves allow customized bending of the cannula, and invitro bending of the cannula. At the time of the invention it would have been obvious to one having ordinary skill in the art to add the Schroeppel nitinol sleeve to the Walker device to allow the Walker device to be bent while inside the body or to be bent into a custom shape. Monter et al. discloses one can add a Teflon sleeve to substantially cover the length of a cannula, so the cannula would gain the added properties of Teflon. Monter et al. mentions Teflon is waterproof and does not melt until 600C. Both of these properties would be advantageous to add to the Walker device because the waterproofing would retard any type of oxidation of the guideline and the high melting temperature would allow the Walker tool to be easily sterilized by high heat sterilization techniques. Additionally, Teflon also has good shrinkability, very low coefficient of friction, and high biocompatibility. At the time of the invention it would have been obvious to one having ordinary skill in the art to add a Teflon sleeve as taught by Monter et al. to the combined Walker guideline assembly, because Teflon has beneficial surgical properties for a cannula as supported by Monter et al. '872 including easy

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heat-shrinkability, waterproofing, high melting temperature, inertness, flexibility, and biocompatibility.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5360341 A	Method and appliance for promoting the healing of oral tissues
US 6033412 A	Implantable bone distractor for incremental bone adjustment
US 6258083 B1	Viewing surgical scope for minimally invasive procedures
US 6270516 B1	Repair apparatus for use in surgical procedures


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A Roberts whose telephone number is (703) 305-7558. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

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12/01/03



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